

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 51328-00001	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/US04/31202	International filing date (<i>day/month/year</i>) 22 September 2004 (22.09.2004)	(Earliest) Priority Date (<i>day/month/year</i>) 23 September 2003 (23.09.2003)
Applicant EPINEX DIAGNOSTICS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box No. II)

3. ☐ Unity of invention is lacking (See Box No. III)

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 2

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☒ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/31202

Box IV TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

The technical features mentioned in the abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

NEW ABSTRACT

A rapid immunochromatographic assay system is provided for measuring both glyated albumin and total albumin. The immunochromatographic assay system is comprised of a cassette that contains the test strips and testing reagents and a measurement device that automatically reads, calculates and displays the test results. The test strip comprises a solid phase support (1) to which antibody to glyated albumin has been fixed to the support as a band (2). A sample application pad (3) contacts a conjugate pad (4) containing microparticles coated with anti-glyated albumin antibody. A control band (5) is provided to bind excess unreacted microparticles. A reservoir pad (6) is provided at the distal end to absorb excess sample fluid. The measurement device can be either a reflectance spectrometer or fluorometer. The level of glyated albumin is expressed as a percentage of the total albumin present in blood. The results of tests that are performed over a period of time are stored in the instrument's memory and presented in a numerical or graphical format so that an individual patient's glyated albumin level can be monitored over time.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/31202

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G01N 33/558

US CL : 436/514

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : Please See Continuation Sheet

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,248,598 B1 (BOGEMA) 19 June 2001 (19.06.2001), see entire document.	1-26
A	US 5,981,298 A (CHUDZIK et al) 09 November 1999 (09.11.1999), see entire document.	1-26
A	US 5,962,336 A (SUN) 05 October 1999 (05.10.1999), see entire document.	1-26

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

12 December 2004 (12.12.2004)

Date of mailing of the international search report

27 DEC 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Christopher L. Chin *J. Roberts for*
Telephone No. (571) 272-1600

INTERNATIONAL SEARCH REPORT

Internat. application No.
PCT/US04/31202

Continuation of B. FIELDS SEARCHED Item 1:

422/55, 56, 57, 58;

435/287.1, 287.2, 287.7, 287.8, 287.9, 288.7, 805, 810, 970;

436/169, 513, 514, 518, 530, 805, 810

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
LOUIS C. CULLMAN
PRESTON GATES & ELLIS, LLP
1900 MAIN STREET, SUITE 600
IRVINE, CA 92614-7319

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 51328-00001		Date of mailing <i>(day/month/year)</i> 27 DEC 2004
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US04/31202	International filing date <i>(day/month/year)</i> 22 September 2004 (22.09.2004)	Priority date <i>(day/month/year)</i> 23 September 2003 (23.09.2003)
International Patent Classification (IPC) or both national classification and IPC IPC(7): G01N 33/558 and US Cl.: 436/514		
Applicant EPINEX DIAGNOSTICS, INC.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Christopher L. Chin <i>J. Roberts for</i> Telephone No. (571) 272-1600
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Form PCT/ISA/237 (cover sheet) (January 2004)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

Internat application No.

PCT/US04/31202

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

Internal application No.
PCT/US04/31202

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 1-26 YES

Claims NONE NO

Inventive step (IS)

Claims 1-26 YES

Claims NONE NO

Industrial applicability (IA)

Claims 1-26 YES

Claims NONE NO

2. Citations and explanations:

Claims 1-26 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an immunochromatographic system and method for monitoring glycosylated albumin with the specific limitations of claims 1-26.

Claims 1-26 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.